PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Gregory S. Kelley	Confirmation No.:	8007
Serial No.:	10/820,659	Examiner:	Christopher Koharski
Filing Date:	April 8, 2004	Group Art Unit:	3763
Docket No.:	1001.1755101	Customer No.:	28075

For: MEDICAL DEVICES INCLUDING AERATED ADHESIVE BONDS AND METHODS OF FORMING THE SAME

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on December 26, 2007 and of the Notice of Panel Decision from Pre-Appeal Review dated February 7, 2008. Applicant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $510.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Boston Scientific Scimed, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Mail Stop A150, Maple Grove, Minnesota 55311-1566. An assignment from the inventors, Henry J. Pepin, Martin R. Willard, Pu Zhou and Greg Kampa, conveying all right, title and interest in the invention to SciMed Life Systems, Inc., has been recorded at Reel 015196, Frame 0922, and a Change of Name to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Frame 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-4 and 7 stand finally rejected under 35 U.S.C. § 102(e) as being anticipated by Deniega et al., US Patent Publication No. 2004/0064129 (hereinafter "Deniega"). Claims 5-6, 8, and 13 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Deniega in view of Ferrera et al., US Patent Publication No. 2001/0026666 (hereinafter "Ferrera"). Claims 9-12 stand finally rejected under 35 U.S.C § 103(a) as being unpatentable over Deniega in view of Jauchen et al., U.S. Patent No. 6,180,544 (hereinafter "Jauchen"). Claims 14-15 stand finally rejected under 35 U.S.C § 103(a) as being unpatentable over Deniega. Claims 16-18 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Deniega in view of Klima et al., US Patent Application No. 2001/0020161 (hereinafter "Klima"). Claims 19-38 are withdrawn as being directed to non-elected subject matter. Claims 1-18 are being appealed.

IV. STATUS OF AMENDMENTS

No After Final Response was filed.

V. SUMMARY OF CLAIMED SUBJECT MATTER[1]

The invention relates to medical devices formed by bonding together medical device components. More particularly, the invention relates to medical devices formed by bonding together medical device components using aerated adhesives. As shown in Figures 3-5, an aerated adhesive layer 52 can be positioned between an outer portion 44 and an inner portion 48.

Turning now to the claims, independent claim 1 recites a medical device comprising a first component (Figures 3-4, reference number 38) having an outer surface (Figures 3-4, reference number 42) including an outer engagement portion (Figures 3-4, reference number 44), a second component (Figures 3-4, reference number 40) having an inner surface (Figures 3-4, reference number 46) including an inner engagement portion (Figures 3-4, reference number 48) (Specification page 8, lines 15-20), the inner engagement portion configured to fit over the outer engagement portion (Specification page 10, lines 8-9), and an aerated adhesive layer (Figures 3-4, reference number 52) positioned between the inner engagement portion and the outer engagement portion (Specification page 9, lines 21-22), wherein the medical device is a catheter (Figure 1, reference number 10) (Specification page 4, line 22).

Dependent claims 2-8, and 13 recite the medical device of claim 1, wherein the aerated adhesive layer comprises a light-curable adhesive, resists delamination, absorbs stresses resulting from curing, comprises distensible regions, comprises a plurality of voids, and has an effective density that is about 25 to about 50 percent less than a density of the adhesive material itself (Specification page 10, line 20 through page 11, line 17). Dependent claims 9-12 recite the medical device of claim 1, wherein the voids in the aerated adhesive layer include an inert gas (Specification page 10, line 15 through page 11, line 10).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-4 and 7 are patentable under 35 U.S.C. § 102(e) over Deniega et al. (US 2004/0064129).

B. Whether claims 5-6, 8, and 13 are patentable under 35 U.S.C. § 103(a) over Deniega et al. in view of Ferrera et al. (US 2001/0026666).

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[1] The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

C. *Whether claims 9-12 are patentable under 35 U.S.C § 103(a) over Deniega et al. in view of Jauchen et al. (U.S. Patent No. 6,180,544).*

D. *Whether claims 14-15 are patentable under 35 U.S.C § 103(a) over Deniega et al.*

E. *Whether claims 16-18 are patentable under 35 U.S.C. § 103(a) over Deniega et al. in view of Klima et al. (US 2001/0020161)*

VII. ARGUMENT

A. *Claims 1-4 and 7 are patentable under 35 U.S.C. § 102(e) over Deniega et al. (US 2004/0064129).*

1. Claim 1

Independent claim 1 recites, in part, "an aerated adhesive layer positioned between the inner engagement portion and the outer engagement portion"; emphasis added. Deniega fails to teach such an element. In the Final Office Action at page 3, second paragraph, the Examiner asserts that Deniega discloses "an aerated adhesive layer", pointing to paragraphs 107-109 for support. This portion of Deniega recites:

> Preferably, a suitable type of medical adhesive is applied between the overlapping surfaces of the tube 282 and the tubular section 280, to hold the tubes 280, 282 together. It is contemplated that the adhesive is of the biocompatible variety, such as medical "glue" that is used for closing wounds.

Emphasis added; see paragraph 108. Deniega does not provide any further discussion of suitable adhesives and does not teach an aerated adhesive layer, as is recited in the claims. MPEP 2131 states:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Deniega does not teach an aerated adhesive layer and thus fails to teach the identical invention in as complete detail as is contained in the claims. Deniega cannot be seen to anticipate the claims. In the Response to Arguments section of the Final Office Action, at page 7, third paragraph, the Examiner also asserts "that any mentioned biocompatible medical adhesive with have some air

voids present within the layer during manufacture and assembly and therefore qualifies as an aerated adhesive using the broadest reasonable definition..." It appears the Examiner is asserting that the "suitable type of medical adhesive" taught by Deniega is inherently an aerated adhesive. Appellant respectfully disagrees.

If the Examiner is considering the aerated adhesive layer recited in the claims to be inherent in Deniega, Appellant submits that there is no basis for such an interpretation. MPEP 2112 IV. states:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is **necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)...
>
> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

(Emphasis added). Appellant submits that the claimed aerated adhesive layer is not necessarily present in Deniega. The Examiner has not provided any basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic of being aerated necessarily flows from the teachings of Deniega. The Examiner's assertion that any biocompatible medical adhesive will have some air voids present within the layer during manufacture and assembly is unsupported by any teaching or suggestion in Deniega. Additionally, the Examiner has failed to provide any technical reasoning to support the assertion. It appears the Examiner may be considering that the "suitable", "biocompatatible" adhesive of Deniega could be modified to be aerated, which is not a proper basis for an anticipation rejection.

The Examiner further asserts that the specification lacks any specific definition of an aerated adhesive. The Examiner's attention is directed to the specification at, for example, page 11, lines 2-17:

> The aerated adhesive layer 52 includes a plurality of voids 54 that can be formed in a variety of ways. In some embodiments, the voids 54 can be formed by metering an inert gas into the adhesive stream while applying the adhesive to the surfaces to be joined.
>
> Other methods of forming the voids 54 include metering the adhesive and inert gas through a mixing tube.
>
> In some embodiments, the voids 54 can include an inert gas at ambient or above-ambient pressure. In particular embodiments, the voids 54 contain nitrogen gas at a pressure that is in the range of about 2 psig to about 15 psig.
>
> The voids 54 can provide distensible regions within the aerated adhesive layer 52 that can distend or deform in response to stresses caused by the adhesive shrinking while curing. The voids 54 can vary in size, but in some embodiments the voids 54 can have an average diameter of about 0.001 inch. In some embodiments, the aerated adhesive layer 52 can include an amount of voids 54 that is in the range of about 25 to about 50 volume percent. The aerated adhesive layer 52 can have a density that is reduced by about 25 to about 50 percent with respect to a density of the adhesive itself without any aeration.

The specification thus provides a specific definition and explanation of an aerated adhesive. Deniega does not teach such an aerated adhesive. Deniega is silent regarding the methods of producing the "biocompatible adhesive" and thus does not teach that the adhesive layer is prepared in a manner that would be expected to produce voids and thus be considered aerated. Appellant submits that it is not necessarily the case in preparing and applying an adhesive layer that voids are introduced into the adhesive. Indeed, in many manufacturing processes, one would expect the introduction of an inadvertent void to be relatively rare. Such a void might well reduce the strength of the bond or, where such a feature is desired, the transparency or other optical properties of the finished piece and thus be grounds for rejecting the piece in the inspection process. In Appellant's experience, which Appellant has no reason to think is uncommon, it is also quite easy to use an off-the-shelf adhesive to attached two components without introducing any voids into the adhesive.

The Examiner appears to be taking Official Notice of this asserted fact. Appellant submits that the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. Pursuant to MPEP 2144.04(C), Appellant respectfully traverses the taking of Official Notice and requests the Examiner provide documentary evidence

supporting the rejection if the rejection is maintained. For at least the reasons set forth above, Deniega fails to teach each and every element of independent claim 1 and thus cannot be deemed to anticipate the claim.

2. Claims 2-4, 7

The Examiner has not separately addressed dependent claims 2-4 and 7, thus it appears the Examiner is relying on an asserted inherent property of the adhesive of Deniega as the basis for the rejection. As discussed above, Deniega fails to teach an aerated adhesive, as recited in independent claim 1, from which claims 2-4 and 7 depend. Deniega is silent regarding the properties of the "suitable", "biocompatible" adhesive used in their device. Appellant submits that because Deniega fails to teach an aerated adhesive, there is no reasonable expectation that the generic biocompatible adhesive of Deniega would inherently resist delamination, absorb stresses resulting from curing of the aerated adhesive, comprise distensible regions, or comprise a plurality of voids, as recited in claims 2-4 and 7, respectively.

As discussed, above, Appellant submits that the claimed aerated adhesive layer is not necessarily present in Deniega. Further, Deniega fails to teach the adhesive layer as having the specific properties of the aerated adhesive layer recited in claims 2-4 and 7. The Examiner has not provided any basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics of resisting delamination, absorbing stresses resulting from curing of the aerated adhesive, comprising distensible regions, or comprising a plurality of voids necessarily flows from the teachings of Deniega. The Examiner's assertion that any biocompatible medical adhesive will have some air voids present within the layer during manufacture and assembly is unsupported by any teaching or suggestion in Deniega. Additionally, the Examiner has failed to provide any technical reasoning to support the assertion. It appears the Examiner may be considering that the "suitable", "biocompatatible" adhesive of Deniega could be modified to have the characteristics recited in dependent claims 2-4 and 7, which is not a proper basis for an anticipation rejection. For at least the reasons set forth above, Deniega fails to teach each and every element of dependent claims 2-4 and 7 and thus cannot be deemed to anticipate the claims.

B. Claims 5, 6, 8, and 13 are patentable under 35 U.S.C. § 103(a) over Deniega in view of Ferrera.

1. Claims 5, 6

Dependent claims 5 and 6 recite further limitations to the aerated adhesive layer of independent claim 1. As discussed above, Deniega fails to teach, expressly or inherently, an aerated adhesive layer. The Examiner asserts that Ferrera teaches catheter components that are assembled with an aerated light curable epoxy adhesive, pointing to paragraph 14 for support. Ferrera does not teach an aerated adhesive, but rather teaches "an adhesive, such as an epoxy, a UV curable adhesive, or a cyanoacrylate adhesive"; see paragraph 14. No teaching or suggestion of an aerated adhesive is found in Ferrera. Further, there is no basis in fact and/or technical reason to support the Examiner's assertion that Ferrera teaches an aerated adhesive. The Examiner has not met his burden of providing the rationale or evidence tending to show inherency. See MPEP 2112 IV.

MPEP 2143.03 states:

> "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

As discussed above, Deniega does not teach, expressly or inherently, an aerated adhesive. Ferrara likewise fails to teach this element. The teaching of Ferrara that the adhesive may be "an epoxy, a UV curable adhesive, or a cyanoacrylate adhesive" does not provide any factual or technical reason that the adhesive necessarily be an aerated adhesive.

Further, the Examiner has not provided any reasoning for why one of ordinary skill in the art would have been motivated to modify the devices of Deniega and/or Ferrera to include an aerated adhesive, as recited in claims 5 and 6. The Examiner appears to be asserting that one could modify the references to include an aerated adhesive. This is not a proper grounds for obviousness. MPEP 2143.01, sections III and IV state:

> The mere fact that references can be combined or modified does not render the resultant combination obvious unless **>the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of

> ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").<
>
> ...
>
> A statement that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). **'">[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).<

Neither Deniega nor Ferrera teaches or suggests, singly or together, each and every element of the claimed invention. Further, the Examiner has provided no articulated reasoning with some rational underpinning to support the conclusion of obviousness. For at least these reasons, Appellant respectfully submits that the combination of Deniega and Ferrera cannot be seen to render claims 5-6 obvious.

2. Claims 8, 13

Dependent claims 8 and 13 recite further limitations on the plurality of voids and effective density of the aerated adhesive layer, respectively. The Examiner acknowledges that neither Deniega nor Ferrera teaches the claimed voids and densities, but asserts that it would have been obvious to construct the aerated-adhesive with the void space and density for optimal joining performance, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

First, as discussed above, neither reference teaches or suggests an adhesive that is aerated or that has voids. Second and in part due to the fact that neither reference teaches or suggests an adhesive that is aerated or has voids, neither reference teaches or suggests that the percent volume of the voids or the effective density of the adhesive layer relative to the adhesive material is a result effective variable and thus a variable for which there is an optimum non-zero value. There is thus no teaching or suggestion of an aerated adhesive nor is there a suggestion or motivation to

create an aerated adhesive found in the cited references. Further, neither references teaches or suggests that having voids or a particular density would create an optimal joining performance. The only indication of such "optimizing" is found in Appellant's specification. Appellant submits that one of ordinary skill in the art would have no reason for "optimizing" a void space and density of an aerated adhesive based solely on the teachings of Deniega and Ferrera because neither reference teaches or suggests anything regarding an aerated adhesive. Without a teaching or suggestion of aerating the adhesive layer in either Deniega or Ferrera, one of ordinary skill in the art would have no way of knowing that modifying properties of an aerated adhesive layer would result in optimization. The instant specification contains the only reference to an aerated adhesive layer. Appellant submits that the Examiner's reliance on the instant specification for motivation to combine or modify references is not a proper basis for an obviousness rejection.

As discussed above, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007). Appellant submits that modifying Deniega and/or Ferrera to include an aerated adhesive would not have been predictable to one of ordinary skill in the art. The Examiner has not provided any evidence or rational reasoning to support such a conclusion.

C. Claims 9-12 are patentable under 35 U.S.C § 103(a) over Deniega in view of Jauchen.

As an initial matter, Appellant submits the Jauchen reference is not a proper reference. To rely on a reference under 35 U.S.C. § 103, the reference must be analogous prior art. MPEP 2141.01(a) states:

> "Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed. " *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

The field of Jauchen, self-stick plaster bandages and the like, is not in the field of the present application, directed to catheters. Moreover, the Jauchen reference cannot be said to be

reasonably pertinent to the particular problem that the inventor of the present application is concerned with. Jauchen is directed to air-permeable, self-adhesive coatings for bandages, with the focus on "high adhesive strength and good permeability to air and water vapour" and skin compatibility. See column 4, lines 11. Appellant submits that such teachings are not reasonably pertinent to the field of the claimed devices, which involve bonding medical device components together with an adhesive that resists stresses caused by adhesive curing. Appellant therefore respectfully submits that it is improper to rely on Jauchen as a reference under 35 U.S.C. § 103.

Notwithstanding the impropriety of the combination of references, the rejection of claims 9-12 over Deneiga in view of Jauchen nevertheless fails to establish a *prima facie* case of obviousness because there is no suggestion or motivation to modify the reference or combine the reference teachings. As discussed above, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007). Appellant submits that modifying Deniega to use the adhesive of Jauchen would not have been predictable to one of ordinary skill in the art.

The Examiner argues that it would have been obvious to use the adhesive of Jauchen with the catheter of Deniega because the adhesive allows for improved joining. However, Jauchen teach their air and water permeable adhesive for providing good skin compatibility and a cushioned effect, which are desirable properties for bandages. Jauchen is directed to providing an adhesive bond between a bandage and human skin, which is why the air and water permeability of the adhesive is desired. Further, nowhere in Jauchen or Deniega is it suggested that an adhesive that improves joining a bandage with skin would be desirable in the catheter of Deniega.

Deniega teach that their joining techniques are quite adequate and do not recognize the problem that the inventor of the present application recognizes of potential delamination of the adhesive joint. Correspondingly, there is no teaching that the adhesive of Jauchen, which improves the air- and water vapor-permeability and adhesion of a bandage to skin, would similarly improve joining between two catheter components. Because the foamed adhesive of Jauchen incorporates a substantial volume of air or other gasses in the form of voids or pockets, its strength per unit volume is necessarily lower than that of a non-foamed adhesive of the same material.

The improved adhesion of a bandage to skin reported by Jauchen therefore must come

from an improved interface between the foamed adhesive and the skin. Foaming an adhesive produces an adhesive material with an irregular surface that is easily conformable, and one can infer that such a surface increases the surface area of adhesive that is actually sticking to the skin and that the improved adhesion reported comes from this increased area of adhesive that is in contact with the irregular surface of the skin. One also notes that the adhesive layer of the bandage, when it is stuck to the skin, is in a solid (and not a liquid) state. Thus one can see that the factors which make the foamed adhesive an improved adhesive for the purposes of Jauchen are inapplicable to the manufacture of catheters. In the manufacture of catheters, such as those of Deniega, the two components are fixed together with the adhesive in a liquid state and the adhesive is then cured with the components in place. There is thus no reason to suppose that a foamed adhesive would produce improved joining in the manufacture of a catheter. Additionally, there is no reasonable expectation of success in using the foamed adhesive of Jauchen in the manufacture of a catheter as taught by Deniega. In particular, Jauchen specifically teach the advantages in making a bandage adhesive, in having the adhesive be air- and water vapor-permeable, and providing a cushioning effect. Appellant submits that one of ordinary skill in the art would not interpret such advantages as being pertinent or helpful in the manufacture of a catheter as taught by Deniega. Appellant therefore respectfully submits that there is no motivation to combine the references and, consequently, that there is no *prima facie* case of obviousness. For at least this reason, Appellant respectfully submits that the rejection of claims 9-12 is improper.

D. Claims 14-15 are patentable under 35 U.S.C. § 103(a) over Deniega

No *prima facie* case of obviousness has been made because each and every claim element is not taught or suggested by the cited prior art, nor is there any suggestion or motivation to arrive at the claimed inventions from the prior art. Claims 14-15 depend from claim 1, which recites "an aerated adhesive layer," which, as described above with respect to the § 102 rejection of claim 1, is not disclosed by Deniega. Further, there is no suggestion or motivation for one of ordinary skill in the art to modify Deniega to include an aerated adhesive.

MPEP 2143.03 states that all words in a claim must be considered in judging the patentability of that claim against the prior art, citing *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Because Deniega fails to teach an aerated adhesive, as recited in independent claim 1, from which claims 14-15 depend, Deniega cannot be seen to teach each

element of claims 14-15. Further, as discussed at length above, there is no motivation for one of ordinary skill in the art to modify Deniega to include an aerated adhesive.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to adjust the adhesive layer of Deniega to achieve a desired thickness for optimal joining and reliability. However, "a particular parameter must be first recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." MPEP 2144.05 citing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Appelant can find no indication in Deniega that the gap between the two tubes is recognized as a result-effective variable; optimization of the gap therefore cannot be regarded as routine. To the contrary, Deniega teaches "Preferably, the tubular section 280 has an outer diameter of about 0.042 inches and has an inner diameter sized so that the distal end 285 of the tube 282 fits snugly within the proximal end 287 of the lumen 281, as shown in Figure 26A." See paragraph 110. In other words, not only is the gap between these two tubes not a result-effective variable, it isn't even a variable in the thinking of Deniega, and it preferably doesn't even exist.

Further, Appellant submits that one of ordinary skill in the art would not consider the ranges claimed in claims 14-15 as being optimal for the adhesives disclosed by Deniega. As discussed at page 1, line 16 through page 2, line 2 of the specification, certain adhesives can exhibit shrinkage upon curing, which results in stresses building up in the adhesive layer. One solution (i.e., the prior art solution) to this is to limit the maximum thickness of the adhesive layer. Thus an optimal thickness for the adhesives in Deniega would not be at least about .001 inch (as recited in claim 14) or in the range of about .002 inch to about .008 inch (as recited in claim 15), but as thin as practicable. This is consistent with the teaching of Deniega cited above that the one tube "fits snugly" within the other. For at least these reasons, Appellant submits that no *prima facie* case of obviousness has been made with respect to claims 14-15. For at least this reason and for the reason that these claims depend from claim 1, which Appellant submits is allowable, and contain additional elements, Appellant respectfully submits that these claims are in condition for allowance as well.

E. Claims 16-18 are patentable under 35 U.S.C. § 103(a) over Deniega et al. in view of Klima

Claims 16-18 depend from claim 1 and contain additional elements. As discussed above, Deniega does not disclose or suggest an aerated adhesive as recited in claim 1. Klima also fails to teach or suggest an aerated adhesive. Thus, even if one were to combine the teachings of Deniega and Klima, one would not arrive at the medical device as recited in claims 16-18. For at least these reasons, Appellant respectfully submits that these claims are in condition for allowance.

F. Conclusion

For the reasons stated above, the rejections of claims 1-18 under 35 U.S.C. §§ 102(e) and 103(a) should be reversed.

Respectfully submitted,

Gregory S. Kelley

By his attorney,

Date: 4/7/08

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VIII. CLAIMS APPENDIX

1. A medical device, comprising:

a first component having an outer surface including an outer engagement portion;

a second component having an inner surface including an inner engagement portion, the inner engagement portion configured to fit over the outer engagement portion; and

an aerated adhesive layer positioned between the inner engagement portion and the outer engagement portion,

wherein the medical device is a catheter.

2. The medical device of claim 1, wherein the aerated adhesive layer resists delamination between the aerated adhesive layer, the inner engagement portion and the outer engagement portion.

3. The medical device of claim 1, wherein the aerated adhesive layer absorbs stresses resulting from curing of the aerated adhesive.

4. The medical device of claim 1, wherein the aerated adhesive layer comprises distensible regions.

5. The medical device of claim 1, wherein the aerated adhesive layer comprises a light-curable adhesive.

6. The medical device of claim 5, wherein the light-curable adhesive comprises an adhesive selected from the group consisting of acrylic, epoxy, acrylic/epoxy, and acrylic/urethane based adhesives.

7. The medical device of claim 1, wherein the aerated adhesive layer comprises a plurality of voids.

8. The medical device of claim 7, wherein the plurality of voids comprise at least about 25 percent volume of the aerated adhesive layer.

9. The medical device of claim 7, wherein the voids include an inert gas.

10. The medical device of claim 9, wherein the inert gas comprises N_2.

11. The medical device of claim 9, wherein the inert gas is at ambient pressure.

12. The medical device of claim 9, wherein the inert gas is at greater than ambient pressure.

13. The medical device of claim 1, wherein the aerated adhesive layer has an effective density that is about 25 to about 50 percent less than a density of the adhesive material itself.

14. The medical device of claim 1, wherein a gap between the outer surface of the first component and the inner surface of the second component is at least about 0.001 inch.

15. The medical device of claim 1, wherein the aerated adhesive layer has an average thickness that is in the range of about 0.002 inch to about 0.008 inch.

16. The medical device of claim 1, wherein the first component comprises an elongate shaft and the second component comprises a hub.

17. The medical device of claim 1, wherein the first component comprises an elongate shaft and the second component comprises a strain relief.

18. The medical device of claim 1, wherein the first component comprises a strain relief and the second component comprises a hub.

IX. EVIDENCE APPENDIX

There is no evidence.

X. RELATED PROCEEDINGS APPENDIX

There are no related appeals or interferences.